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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,882		04/05/2001	Jon Elliot Adler	P 0279152 2000-013	3758
909	7590	07/02/2002			
PILLSBUI	RY WINT	THROP, LLP	EXAMINER		
P.O. BOX 10500 MCLEAN, VA 22102				BRANNOCK, MICHAEL T	
MCLEAN,	VA 2210	2			
				ART UNIT	PAPER NUMBER
				1646	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/825,882 Applicant(s)

Adler et al.

Michael Brannock, Ph.D

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The MAILING DATE of this communication appear	rs on the cover sheet with the correspondence address					
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM						
THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1 136 (a) In I	no event, however, may a reply be timely filed after SIX (6) MONTHS from the					
mailing date of this communication - If the period for reply specified above is less than thirty (30) days, a reply within the						
- If NO period for reply is specified above, the maximum statutory period will apply as	nd will expire SIX (6) MONTHS from the mailing date of this communication.					
 Failure to reply within the set or extended period for reply will, by statute, cause the Any reply received by the Office later than three months after the mailing date of th 						
earned patent term adjustment. See 37 CFR 1.704(b) Status						
1) $\overline{X}^{[]}$ Responsive to communication(s) filed on <u>May 9, 2</u>	002					
2a) This action is FINAL . 2b) X This act	tion is non-final.					
3) Since this application is in condition for allowance e closed in accordance with the practice under Exp						
Disposition of Claims						
4) X: Claim(s) <u>1-137</u>	is/are pending in the applica					
	is/are withdrawn from considera					
	is/are allowed.					
	is/are rejected.					
	is/are objected to.					
8) 🗓 Claims <u>1-137</u>	are subject to restriction and/or election requirem					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/a	are a $\overline{}$ accepted or b) $\overline{}$ objected to by the Examiner.					
Applicant may not request that any objection to the draw						
	is: a) approved b) disapproved by the Examiner.					
If approved, corrected drawings are required in reply to t						
12) The oath or declaration is objected to by the Examine	er.					
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgement is made of a claim for foreign price	ority under 35 U.S.C. § 119(a)-(d) or (f).					
a)☐ All b) ☐ Some* c) ☐None of:						
1. Certified copies of the priority documents have	been received.					
2. Certified copies of the priority documents have	been received in Application No					
3. Copies of the certified copies of the priority documents application from the International Bureau	cuments have been received in this National Stage					
*See the attached detailed Office action for a list of the	, , , ,					
14) Acknowledgement is made of a claim for domestic p	riority under 35 U.S.C. § 119(e).					
a) 📑 The translation of the foreign language provisional	application has been received.					
15) Acknowledgement is made of a claim for domestic p	riority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)						
1) Notice of References Cited (PTO-892)	4)interview Summary (PTO-413) Paper No(s)					
2)Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Patent Application (PTO-152)					
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	6) Other					

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DETAILED ACTION

Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-53, 78-80, 82-84, 125-133, drawn to polynucleotides, classified in class 536, subclass 23.5.
 - II. Claims 54-59, drawn to solid phase polynucleotides, classified in class 536, subclass 24.31.
 - III. Claims 60-71, 87-96, drawn to polypetides, classified in class 530, subclass 350.
 - IV. Claims 72-75, drawn to solid phase polypeptides, classified in class 436, subclass 518.
 - V. Claims 76, 77, 134-136, drawn to methods for detecting nucleic acids, classified in class 435, subclass 6.
 - VI. Claims 81 and 86, drawn to transgenic animals, classified in class 800, subclass 8.
 - VII. Claims 85, 97, 101-107, 116, drawn to methods of detecting binding of a compound to a protein, classified in class 435, subclass 7.1.
 - VIII. Claim 98, drawn to antibodies, classified in class 530, subclass 350.
 - IX. Claims 99 and 100, drawn to methods of detecting a polypeptide, classified in class 436, subclass 501.

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X. Claims 108-115, 117, 118, 137, drawn to methods of assaying for tastant signal transduction and/or binding to a ligand, classified in class 435, subclass 7.21.

- XI. Claims 119-124, drawn to methods of representing taste perception, classified in class 800, subclass 3.
- 2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Groups I-IV, VI and VIII are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Groups III and IV can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group II or III, such in gene therapy or as a probe in nucleic acid hybridization assays as in Group V. The polynucleotides of Group II are unrelated to the polypeptides of Groups III and IV. The protein of Group II can be used in materially different methods other than to make the antibody of Group VIII, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group VIII can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or

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therapeutic methods, as in Group IX. The products of Groups II, IV and VI are unrelated to the antibody of Group VIII.

Inventions Group I and Groups II and VI are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful to produce the proteins of Group III and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Further, the intermediate product of Group I and the final products of Groups II and VI are mutually exclusive, e.g. the products of Group I would no longer be useful for recombinant expression in tissue culture cells, MPEP § 806.04(b). Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions of Groups III and IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the

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intermediate product is deemed to be useful to produce the antibody of Group VIII and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Further, the intermediate product of Group III and the final products of Groups IV are mutually exclusive, e.g. the intermediate product can no longer be used to make the antibody Group VIII, MPEP § 806.04(b).

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups V, VII, IX, X and XI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group V requires nucleic hybridization assays, which is not required by any of the other groups. Group VII requires methods of detecting the physical association of ligand and receptor, which is not required by any of the other groups. Group IX requires methods of detecting a polypeptide with an antibody, which is not required by any of the other groups. Group X requires methods of measuring intracellular signal transduction, which is not required of any of the other groups. Group XI requires methods for representing the perception of taste in a mammal, which is not required of any of the other groups.

The polynucleotides of Group I are related to the methods of Groups V, VII, X-XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

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another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I are patentably distinct from each of the methods of Groups V, VII, X-XI because the polynucleotides of Group I can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups V, VII, IX-XI are materially and functionally distinct from the others. Furthermore, the polynucleotides of Group I and the methods of Groups IX are patentably distinct because one is not required for the use of the other.

The polynucleotides of Group II are related to the methods of Groups V and XI as product and process of use. In the instant case the polynucleotides of Group II are patentably distinct from each of the methods of Groups V and XI because the polynucleotides of Group II can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups V and XI are materially and functionally distinct from the others. Furthermore, the polynucleotides of Group II and the methods of Groups VII, IX and X are patentably distinct because one is not required for the use of the other.

The polypeptides of Group III are related to the methods of Groups VIII, IX-XI as product and process of use. In the instant case the polypeptides of Group III are patentably distinct from each of the methods of Groups VIII, IX-XI because the polypeptides of Group III can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups VIII, IX-XI are materially and functionally distinct from

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the others. Furthermore, the polypeptides of Group III and the method of Group V are patentably distinct because one is not required for the use of the other.

The polypeptides of Group IV are related to the methods of Groups VII, IX and XI as product and process of use. In the instant case the polypeptides of Group IV are patentably distinct from each of the methods of Groups VII, IX and XI because the polypeptides of Group IV can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups VII, IX and XI are materially and functionally distinct from the others. Furthermore, the polypeptides of Group IV and the method of Groups V and X are patentably distinct because one is not required for the use of the other.

The transgenic animals of Group VI are related to the methods of Groups VII, IX- XI as product and process of use. In the instant case the transgenic animals of Group VI are patentably distinct from each of the methods of Groups VII, IX- XI because the transgenic animals of Group IV can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups VII, IX- XI are materially and functionally distinct from the others. Furthermore, the transgenic animals of Group VI and the method of Groups V are patentably distinct because one is not required for the use of the other.

The antibodies of Group VIII are related to the methods of Groups VII, IX- XI as product and process of use. In the instant case the antibodies of Group VIII are patentably distinct from each of the methods of Groups VII, IX- XI because the antibodies of Group VIII can be used in ways that are materially and functionally different than each of the methods because, as discussed

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above, each of the methods of Groups VII, IX- XI are materially and functionally distinct from the others. Furthermore, the antibodies of Group VIII and the method of Group V are patentably distinct because one is not required for the use of the other.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

3. Claims 1-137 are generic to a plurality of disclosed patentably distinct species comprising a polypeptide of either SEQ ID NO: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20 and 24 or a polynucleotide of either SEQ ID NO: 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, and 23. Each SEQ ID NO represents a structurally and functionally distinct molecule, the use of one not being required for the use of any other. Further, although a search of one SEQ ID NO may overlap that of another, no two searches would be coextensive, and nor could one search be relied upon to provide art that is anticipatory or might render obvious any other SEQ ID NO; and to search all species in a single application would be unduly burdensome. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, such species being appropriate to the Group chosen, e.g. if Group I is chosen then an appropriate species would be SEQ ID NO: 1, even though this requirement is traversed.

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4. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. MPEP § 809.02(a).

- 5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner 7.

should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The

examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m.

The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal

communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 30, 2002

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